

REMARKS

Lack of Antecedent Basis

Claims 1-3 were rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to provide support or antecedent basis for the phrase “wherein the extract comprises 1.5 mg of berberine alkaloid per ml of extract”. Claim 1 has been amended to delete the phrase in question. Accordingly, claim 1, as amended, satisfies 35 U.S.C. § 112, first paragraph.

Written Description

Claims 1-3 were also rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement. Specifically, the Examiner alleges that the applicant has not set forth a representative number of examples in order to reasonably verify possession of such a potentially large numbers of extracts.

Claim 1 has been amended to define the extract as a hydroalcoholic extract of the bark and twigs of plants from the *Mahonia aquifolium* family, wherein the extract is obtainable by extracting the bark and twigs of the *Mahonia aquifolium* plant with a hydroalcoholic solvent at a pressure of 3-6 psi and a temperature of 40°C-50°C. The applicants disclose that such extractions contain approximately 1.5 mg of berberine alkaloid per ml of extract (page 5, lines 23-25). In contrast, typical alcohol extracts contain about 0.09 mg of beberine alkaloid per ml of extract (page 5, lines 25-28).

Applicants argue that examples are not required under U.S. law. In *In re Borkowski*, the Court held that the specification need not contain an example if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without an undue amount of experimentation (*In re Borkowski*, 422 F.2d 904, 908, 164 U.S.P.Q. 642,

645 (CCPA 1970)). The applicant clearly discloses how to perform the extraction in order to obtain extracts with higher concentrations of bebrerine alkaloid (*see* pages 4-5 for a description of the extraction process). Therefore, claims 1-3 satisfy the written description requirement.

Indefiniteness

Claims 1-3 were rejected under 35 U.S.C. § 112, second paragraph for allegedly being indefinite. Specifically, the Examiner alleges that the term “extract” was indefinite because it did not adequately delineate its metes and bounds. Claim 1 has been amended to define the solvent system used to obtain the extract as well as the reaction conditions under which the extract is obtained. Accordingly, claims 1-3 are definite.

Favourable reconsideration and allowance of the present application are respectfully requested.

Respectfully submitted,

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